

Serial No.: 09/919,195
Docket No.: 17293DIV
Filed: July 31, 2001

composition comprises a pharmacologically acceptable vehicle suitable for treatment of lung pathologies and a therapeutically effective amount of the RAR β antagonist. Support for the amendments can be found on pages 5, 6, 7 and 12 of the specification.

Rejections Pursuant to 35 USC § 102

Currently pending claims 1-8 are composition claims. Claims 9-23 are drawn to an aerosol. Claims 13-28 are drawn to methods of treatment.

The Examiner has rejected all these claims as allegedly anticipated by one of US Patents 5,776,699, 6,218,128, and 6,228,848, to Klein. The Examiner explained that Klein discloses compounds that are RAR antagonists and not specific to RAR α or RAR γ .

In order to anticipate, a single prior art reference must be shown to contain each and every limitation of the claimed invention. The Examiner has not shown (or attempted to show) that Klein discloses a method to increase the gas-exchange surface area of a mammalian lung (claims 13-28), nor has the Examiner shown (or attempted to show) that Klein discloses an aerosol for pulmonary delivery of a pharmaceutical composition (claims 9-12). With regard to claims 1-8, the Klein references do not disclose a "therapeutically effective amount", defined on page 7 of the specification, of a RAR antagonist having "specific RAR modulating activity", as this term is defined on pages 5 and 6 of the present specification. Since Klein fails to disclose each limitation of any of the claims, none of these patents anticipate the presently pending claims, and Applicants respectfully ask the Examiner to reconsider and withdraw this rejection.

Rejections Pursuant to 35 USC § 103

The Examiner has rejected claims 1-28 as rendered obvious by one or more of US Patents 5,776,699, 6,218,128, and 6,228,848, to Klein. The Examiner explained that Klein discloses compounds that are RAR antagonists and not specific to RAR α or RAR γ .

The present invention is directed to methods, compositions, and aerosols for the treatment of pathologies involving alveolar destruction. As an initial matter, the Examiner has not demonstrated that Klein in any way suggests the use of RAR antagonists to treat pulmonary disorders. Furthermore, Applicant has been unable to find any suggestion in Klein of the use of an aerosol for the treatment of such disorders. Without such a suggestion, pending claims 9-28 cannot properly be held to be obvious.

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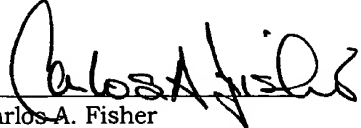
Although the Examiner has alleged that column 5, line 44 through column 7 line 40 of the Klein patents disclose compounds that are RAR antagonists and not specific to RAR α or RAR γ , Applicants are unable to find such a disclosure in the cited patents. The Klein patents do disclose methods of treating "a pathological condition" comprising administering "a retinoid antagonist or negative hormone capable of binding to one of the following retinoic acid receptor subtypes: RAR α , RAR β and RAR γ ". U.S. Patent 5,776,699, column 5, lines 63-66. However, there is no disclosure that indicates that the antagonist be capable of binding since there is no disclosure that specifies that such a compound necessarily have "specific RAR modulating activity", or that it may be specifically antagonistic to RAR β receptor activity and not to RAR α (see e.g., claim 2) or RAR γ (claim 3). Finally, there is no disclosure or suggestion in the Klein patents of a composition such as that of claims 1-8, which is present in a therapeutically effective amount (page 7 of the specification) ; that is, that it be present in a dose sufficient to decrease the rate of alveolar destruction or to promote the growth of alveolar septa in a mammal.

REMARKS

For these reasons, Applicants respectfully submit that the claims are in composition for allowance, and respectfully request that the Examiner issue a Notice to that effect. Should any fees be due in with this Reply, please use our Deposit Account No. 01-0885.

Respectfully submitted,

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MARKED UP VERSION OF THE CLAIM AMENDMENT

1. (Amended) A composition for the treatment or prevention of alveolar destruction in a mammal comprising a therapeutically [pharmaceutically] effective amount of an RAR β antagonist having specific RAR [specific] modulating activity and a pharmacologically acceptable vehicle suitable for treatment of lung pathologies.